HUMAN SERVICES

DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

Pharmaceutical Services Manual

Pharmacy Provider Application Date

Proposed Amendments: N.J.A.C. 10:51-1.2

Authorized: by Gwendolyn L. Harris, Commissioner,

Department of Human Services.

Authority: N.J.S.A. 30:4D-1 et seq., specifically 6, 7 and 12.

Calendar Reference: See Summary below for explanation of the exception

to the rulemaking calendar requirements of N.J.A.C.

1:30-3.3(a)5.

Agency Control Number: 03-P-08.

Proposal Number: PRN 2003 -427

Submit comments by April 30, 2004 to:

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The agency proposal follows:

Summary

The Division of Medical Assistance and Health Services is proposing amendments to N.J.A.C. 10:51-1.2. The proposed amendments are intended to require pharmacy providers to comply with specific application requirements for approval as participating providers.

Specifically, at N.J.A.C. 10:51-1.2(e), the Division is proposing that the applicant pharmacy, as well as the individual(s) who signs the application, assume responsibility for the accuracy of the information contained in the application.

The proposed amendments at N.J.A.C. 10:51-1.2(g) clarify that, if the date the application was signed is more than 10 calendar days prior to the date the application is received, the effective date of approval for participation shall be the date the retail or institutional permit was issued or the date the application was received by the Division or its fiscal agent, whichever is later.

Finally, the proposed amendment at N.J.A.C. 10:51-1.2(h), informs providers that any application received by the Division or its fiscal agent more than 30 days after the date the application was signed shall be deemed invalid and the submission of a new application will be required.

As the Department has provided a 60-day comment period on this notice of proposal, this notice is exempted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The proposed amendments should have no impact on beneficiaries, as they will continue to receive pharmaceutical services. During State Fiscal Year 2003, an estimated 178,000 beneficiaries received prescriptions each month under the Medicaid program.

The proposed amendments should have a positive impact on the pharmaceutical providers who complete their provider applications properly because they will continue to be reimbursed for services which customers might not otherwise be able to afford. Currently, there are 2,011 pharmacists providing services to Medicaid beneficiaries.

Economic Impact

The proposed amendments should have a positive economic impact on the pharmaceutical providers who complete their provider applications properly because they will continue to be reimbursed for services which customers might not otherwise be able to afford. For pharmaceutical providers who do not comply with the proposed amendments, there will be a delay and/or denial of reimbursement. During State

Fiscal Year 2003, the Division spent approximately \$650,929,883 (Federal and State combined) for approximately 12,000,000 prescriptions.

Federal Standards Statement

Sections 1902(a)(10), 1905(a)12 and 2110(a) of the Social Security Act (42 U.S.C. §1396(a)(10), 1396d(a), and 1397jj) allow a state Medicaid or NJ FamilyCare program to provide pharmaceutical services. Federal requirements regarding disclosure by providers of ownership and control information are contained in Sections 1902(a)38, 1124 and 1126 of the Act (42 U.S.C. §1396a(a)38, 42 U.S.C. 1320a-3, and 42 U.S.C. 1320a-5) and 42 CFR 455.10.

Federal regulations at 42 CFR 455.104 and 42 CFR 440.120 define what may be covered as prescribed drugs. Federal requirements regarding restrictions on coverage are contained in Section 1927(d) of the Act (42 U.S.C. §1396r-8(d)).

Title XXI of the Social Security Act allowed states to establish a children's health insurance program for targeted low-income children. New Jersey elected this option through implementation of the NJ KidCare program. When the rules implementing NJ FamilyCare were concurrently proposed and adopted (see N.J.R. 3603(a), published October 2, 2000), the NJ KidCare program was effectively combined with NJ FamilyCare, without changing the scope of the NJ KidCare program. New Jersey

continues to comply with Federal standards by meeting Federal specifications.

The Division has reviewed the Federal statutory and regulatory requirements and has determined the proposed amendments do not exceed Federal standards.

Jobs Impact

The proposed amendments are not expected to create jobs or cause a loss of jobs in the State of New Jersey.

Agriculture Industry Impact

The proposed amendments are not expected to impact on the agriculture industry.

Regulatory Flexibility Analysis

The proposed amendments will not affect providers other than those who provide pharmaceutical services to beneficiaries. Some of these providers may be considered small businesses, that is, they employ fewer than 100 full-time equivalent employees, under the terms of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The amendments may impose some initial additional recordkeeping, compliance, or reporting requirements on small businesses. These requirements are imposed at the time of application to the State of New Jersey to be a pharmaceutical provider. At

N.J.A.C. 10:51-1.2(e), the Division is proposing that the applicant pharmacy, as well as the individual(s) who sign the application, assume responsibility for the accuracy of the information contained in the application. The proposed amendments at N.J.A.C. 10:51-1.2(g) clarify that if the date the application was signed is more than 10 calendar days prior to the date the application is received, the effective date of approval for participation shall be the date the retail or institutional permit was issued or the date the application was received by the Division or its fiscal agent, whichever is later. accordance with proposed N.J.A.C. 10:51-1.2(h), any application received 30 days after the date it is signed will be rejected and a new application will be required. These timely filing requirements for applicants should affect their planning, but create no additional expense. The providers are already required to maintain records to fully disclose the name of the beneficiary who received the service, date of service, and any additional information as may be required by N.J.A.C. 10:49 and N.J.S.A. 30:4D-1 et seq. This requirement must be equally applicable to all providers regardless of size, since State and Federal law require accurate records.

There should be no capital costs associated with these requirements. Additional professional services are not required by the amendments proposed.

Smart Growth Impact

The Department anticipates that the proposed rulemaking will have no impact on smart

growth in New Jersey or on the implementation of the New Jersey State Development and Redevelopment Plan.

<u>Full text</u> of the proposal follows (additions indicated in boldface <u>thus</u>; deletions indicated in brackets [thus]):

10:51-1.2 Participation of eligible providers

(a) - (d) (No change.)

(e) The pharmacy, as well as the individual(s) who sign the application, shall assume full responsibility for the accuracy of the information contained in the application.

(f) The effective date on which an applicant is approved as a provider shall be:

- 1. The date the applicant's retail or institutional permit was issued; or
- 2. The date the provider application was signed, whichever is later, except as specified in (g) below.

(g) If the date the application was signed is more than 10 calendar days prior to the date the application was received by the Division or its fiscal agent, then the effective date of approval shall be the later of:

- 1. The date the retail or institutional permit is issued; or
- 2. The date the application was received by the Division or its fiscal

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(h) The applicant shall submit a new application if the date the application was received by the Division or its fiscal agent exceeds the date the application was signed by more than 30 calendar days.

Gwendolyn L. Harris, Commissioner Department of Human Services

Date